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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SMITH, TERRI L	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 02/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/728,124	DYJACH ET AL.	
	Examiner	Art Unit	
	Terri L. Smith	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *04 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1–6, 14–20, and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Levine, U.S. Patent 6,865,414.

3. Levine discloses sensing electrical activity in a cardiac chamber and generating a chamber sense signal when a sensed electrical activity exceeds a predetermined threshold (column 5, lines 19–20; column 6, lines 53–59); measuring time intervals between each pair of successive chamber senses (Figs. 3–5; column 11, lines 7–9; column 17, lines 14–16), referred to as BB intervals, the measured BB intervals constituting an BB time series; filtering BB intervals to exclude those BB intervals which are greater or less than a statistic computed from a plurality of preceding BB intervals by a specified threshold value (column 12, line 56–column 12, line 5; column 13, line 64–column 14, lines 1 – 4 and lines 11–18), the excluded BB intervals being deemed to be ectopic BB intervals which are due to ectopic cardiac activity (column 17, lines 9–12); and, computing a heart rate variability metric from the filtered BB intervals (Figs. 3–5 and 7; column 11, lines 62–column 12, lines 1–3); wherein a statistic is a median value (claims 2 and 16), and a weighted average (claims 3 and 17) of a plurality of preceding BB intervals (Fig. 5; column 12, lines 42–64); a chamber senses are ventricular senses (Figs. 2–3 and 7; column 5,

line 27; column 10, lines 43–46; column 15, lines 8–13) and the BB intervals are RR intervals (claims 4 and 18) (Figs. 3–5; column 8, lines 7–13; column 11, lines 33–36); a specified threshold value is a specified number (claims 5 and 19) (Fig. 3) and is a specified percentage of a computed statistic (claims 6 and 20) (Fig. 4; column 11 –column 12, lines 1–10); maintaining a count of the number of detected ectopic beats (claims 14 and 28) (column 1, lines 17–19).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the Examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 7–10 and 21–24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levine, U.S. Patent 6,865,414.

Levine discloses evaluating a present BB interval by comparing a present BB interval to a statistic computed from a plurality of previous BB intervals stored and contains a maximum number N of preceding BB intervals (Figs. 3–7) and excluding a present BB interval as an

ectopic interval if a present BB interval is greater or less than a computed statistic by a specified threshold value and updating after each interval (claims 7 and 21) and removing the oldest interval and storing a present BB interval if a present BB interval was not excluded as ectopic (claims 8 and 22) (Figs. 3–7; columns 11–16, lines 1–16). However, Levine does not disclose expressly the claimed limitations of a first-in-first-out **buffer**, where a buffer contains a maximum number N of preceding BB intervals (claims 7 and 21) and updating a **buffer** after each BB interval is evaluated and updating a **buffer** by removing the oldest interval and storing a present BB interval therein if a present BB interval was not excluded as ectopic (claims 8 and 22) [NOTE: Regarding what Levine does not disclose, the emphasis is on the buffer]. It would have been an obvious matter of engineering design choice to one of ordinary skill in the art at the time the invention was made to modify the microcontroller and its associated circuitry (which perform the limitations of the buffer in the claimed invention) as taught by Levine, to have a first-in-first-out buffer to perform the claimed limitations of the invention as described herein above, because Applicant has not disclosed that a first-in-first-out buffer and its uses thereof provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the microcontroller and its associated circuitry as taught by Levine, because it provides a history record of ectopic events, distinguished by sensing thresholds and timing intervals, giving a valuable diagnostic tool to the physician in optimizing rhythm management therapy.

Therefore, it would have been an obvious matter of engineering design choice to modify the microcontroller and its associated circuitry to obtain the invention as specified in the claim(s).

Similarly, regarding claims 9 and 23, Levine discloses filtering a BB intervals by: excluding a present BB interval as ectopic if a present BB interval is above or below specified upper and lower limit values (Figs. 3–7); excluding a present BB interval as indeterminate if a first-in-first-out buffer for containing a maximum number N of preceding BB intervals contains less than N intervals (column 12, lines 31–46); if a buffer contains N intervals, computing a median value of a plurality of previous BB intervals stored (column 12, lines 42–64); excluding a present BB interval as ectopic if a present BB interval is greater or less than a computed median value by the specified threshold value (column 12, lines 42–64); and, updating after each BB interval is evaluated by: if a present BB interval was not ectopic, removing the oldest interval from a microcontroller and its associated circuitry (buffer) if it contains N intervals and storing a present BB interval therein; and, if a present BB interval was ectopic, removing the oldest interval from a microcontroller and its associated circuitry (buffer) if it contains at least one interval (Figs. 3–7; columns 11–16, lines 1–16). However, Levine does not disclose expressly a first-in-first-out buffer, a buffer contains N intervals, a plurality of previous BB intervals stored in a buffer, updating a buffer, removing the oldest interval from a buffer if a buffer contains N intervals and storing a present BB interval therein. It would have been an obvious matter of engineering design choice to one of ordinary skill in the art at the time the invention was made to modify the microcontroller and its associated circuitry (which perform the limitations of the buffer in the claimed invention) as taught by Levine, to have a first-in-first-out buffer to perform

the claimed limitations of the invention as described herein above, because Applicant has not disclosed that a first-in-first-out buffer provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the microcontroller and its associated circuitry as taught by Levine, because it provides a history record of ectopic events, distinguished by sensing thresholds and timing intervals, giving a valuable diagnostic tool to the physician in optimizing rhythm management therapy.

Therefore, it would have been an obvious matter of engineering design choice to modify the microcontroller and its associated circuitry to obtain the invention as specified in the claim(s).

With respect to claims 10 and 24, Levine discloses a lowest numerical value and a lowest numerical setting (column 12, lines 31–37), but not the number N is three. This provides a clear suggestion Levine can be modified to change the numerical value/setting to the number N is three. The determination of the most appropriate number N by routine experimentation would, therefore, be prima facie obvious to one having ordinary skill in the art.

It would have been an obvious matter of engineering design choice to one of ordinary skill in the art at the time the invention to modify the numerical value/setting to the number N is three to obtain the invention as specified in the claim(s) because it provides a history record of accurate event detection, giving a valuable diagnostic tool to the physician in optimizing rhythm management therapy.

Regarding claims 11–13 and 25–27, Levine discloses a heart rate variability metric is a parameter computed by time-domain filtering of the filtered BB intervals (claims 11 and 25)

(Figs. 2 and 6; column 15, lines 3–6). Levine discloses the claimed invention but does not disclose expressly a heart rate variability metric is a parameter computed by frequency domain analysis (claims 12 and 26) and a statistical surrogate of a frequency component (claims 13 and 27) of the filtered BB intervals. It would have been an obvious matter of engineering design choice to one of ordinary skill in the art at the time the invention was made to modify the microcontroller timing control and bandpass filtering capability as taught by Levine, to have a heart rate variability metric is a parameter computed by frequency domain analysis and a statistical surrogate of a frequency component of the filtered BB intervals, because Applicant has not disclosed that a heart rate variability metric being a parameter computed by frequency domain analysis and a statistical surrogate of a frequency component of the filtered BB intervals provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with the microcontroller timing control and bandpass filtering capability as taught by Levine, because it provides to selectively sense the cardiac signal of interest to deal effectively with the difficult problem of sensing low amplitude signal characteristics of atrial or ventricular events (column 7, lines 25 –33).

Therefore, it would have been an obvious matter of engineering design choice to modify the microcontroller timing control and bandpass filtering capability to obtain the invention as specified in the claim(s).

Conclusion

7. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Terri L. Smith whose telephone number is 571-272-7146. The Examiner can normally be reached on Monday - Friday, between 7:30 a.m. - 4:00 p.m..

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TLS
February 23, 2006
23 February 2003

GEORGE R. EVANISKO
PRIMARY EXAMINER
2/24/6